JUN 1 4 2001

Dräger

K010093

510(k) Summary (Section 16)

Summary of Safety and Effectiveness

Applicants Name and Address

Dräger Medizintechnik GmbH
Moislinger Allee 53-55
D-23542 Lübeck
Germany

Applicants Contact Person

Mr. Ulrich Schröder
Manager Regulatory Affairs

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Applicants US Contact Person

Mr James J. Brennan
Director Regulatory Affairs

Tel. No.: (215) 721-5400
Fax No.: (215) 721-5412

Date the Summary was prepared

January 4, 2001

Device Name

Trade Name:	NIV Option for Evita 4 and Evita 2 dura
Common Name:	Continuous Ventilator
Classification Name:	Ventilator, Continuous (per 21 CFR 868.5895)

Legally marketed device to which Substantial Equivalence is claimed

Evita 4 (K980642)
Manufactured and distributed in the United States by Dräger Medical Inc.

Evita 2 dura (K970165)
Manufactured and distributed in the United States by Dräger Medical Inc.

BiPAP Vision Ventilatory Support System (K982454)
Distributed in the United States by Respironics Inc.

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Description of the Device

The Evita 4 and the Evita 2 dura are both time-cycled microprocessor-controlled intensive care ventilators. Both devices can operate in the mask ventilation mode with the NIV option activated. NIV means *non-invasive ventilation*. The NIV option is available with SW 4.0 for Evita 4 and Evita 2 dura.

With the NIV option activated, the user can switch the ventilator during preparation of the machine into one of two application modes: a) "Tube" application mode, b) "Mask" ventilation mode. The "Tube" application mode corresponds to the regular behavior of the device if the NIV option is not activated. The "Tube" application mode shall be selected, whenever the ventilated patient is intubated.

If the "Mask" application mode is selected, the user gains the option to configure parts of the device integrated monitoring to adapt the device to the specific needs of the mask ventilated patient. The "Mask" application mode shall only be used in cases where the patient is ventilated over a face or nasal mask.

In order to inform the user permanently about the selected mode, the display of the device shows a special symbol, whenever the application mode is set to "Mask". For colour displays the user is also informed by the background colour of the display: In "Tube" mode the background colour of the display is blue, in "Mask" mode the background colour is set to green.

Intended Use

Evita 4 and Evita 2 dura are time cycled, constant volume, long term, intensive care ventilators for adults, children and infants with a body weight of at least 0,5 kg.

Non-invasive ventilation (NIV) is an option for ventilation via a nasal or face mask supporting non-invasive respiratory therapies. NIV adds the choice between mask ventilation and ventilation of intubated patients.

The NIV option extends the range of applications for Evita 4 and Evita 2 dura ventilators as of software version 4.n.

Substantial Equivalence

The intended use of the NIV option for the Evita 4 and Evita 2 dura intensive care ventilators is the same as the predicate devices. The materials and design are also similar to those predicate devices. The technical characteristics of the NIV option do not raise new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the NIV option provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Software design, development and verification was performed in accordance with FDA guidances and company internal standards. Performance testing was conducted using the ASTM F1100-90 standard and other international and company internal standards. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

In summary Dräger Medizintechnik GmbH has demonstrated the NIV option to be safe and effective. The Evita 4 and Evita 2 dura devices with NIV option is considered to be substantial equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2001

Drager Medizintechnik GmbH
c/o Mr. James J. Brennan
Drager Medical, Inc.
3135 Quarry Road
Telford, PA 18969

Re: K010093
Trade Name: Non-Invasive Ventilation NIV Option,
Model 84 14 474
Regulation Number: 868.5895
Regulatory Class: II (two)
Product Code: CBK
Dated: April 11, 2001
Received: May 7, 2001

Dear Mr. Brennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use

Evita 4 / Evita 2 dura with option NIV

$Revision: 1.2 $

Dräger

510(k) Number (if known): K010093

Device Name: __ Evita 4 / Evita 2 dura with option NIV – Non-invasive ventilation.___

Indication For Use:

Evita 4 / Evita 2 dura is a time cycled, constant volume, long term, intensive care ventilator for adults, children and infants with a body weight of at least 0,5 kg.

Non-invasive ventilation is an option for ventilation via a nasal or face mask supporting non-invasive respiratory therapies.
NIV adds the choice between mask ventilation and ventilation of intubated patients.
The NIV option extends the range of applications for Evita 4 and Evita 2 dura ventilators as of software 4.n.

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Division of Cardiovascular & Respiratory Devices
510(k) Number K010093

Prescription Use Only

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